JC04 Rec'd PCT/PTO 21 JUL 2005

PTO-1390 (Rev. 12-2004) Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES

ATTTORNEY'S DOCKET NUMBER 3153US0P DESIGNATED/ELECTED OFFICE (DO/EO/US) See 37 CFR 1.5) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. PCT/JP2004/000754 INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED January 28, 2004 January 29, 2003 TITLE OF INVENTION PROCESS FOR PRODUCING COATED PREPARATION APPLICANT(S) FOR DO/EO/US Kazuhiro OHKOUCHI; Masahiko KOIKE; Hiroyoshi KOYAMA; Naoru HAMAGUCHI Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31).  $\square$ A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. **Ľ** An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7 Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. Cited References 12. V An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

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Other items or information:

Page 1 of 2

Return Postcard; Certificate of Express Mailing; PCT Request; Cover Page International Application; Forms PCT/IB/301,304,306,308; ISR

PTO-1390 (Rev. 12-2004)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO.					ATTORNEY'S DOCKET NUMBER	
101542997 PCT/JP2004/000754				3153US0P		
21. The following fees are submitted:						
a) Basic national fee\$300.00					\$	
b) Examination fee\$200.00					\$	
c) Search fee					\$	
TOTAL OF ABOVE CALCULATIONS = \$1000.00					\$ 1,000.00	
Additional f	ee for specification and opportunity of the formal					
	0 sheets of paper or frac					
Total Sheets Extra sheets		Number of each additional 50 or fraction RATE				
		thereof (round up to a whole number)		·		
37 - 100 =	0 /50 =	0		× \$250.00	\$ 0	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).					\$	
CLAIMS NUMBER FILED		LED	NUMBER EXTRA	RATE	\$	
Total claims	13	- 20 =	0	x \$50.00	\$ O	
Independent cla	ims 2	- 3 =	0	× \$200.00	\$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360.00					\$	
TOTAL OF ABOVE CALCULATIONS =					\$	
Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.					\$	-
SUBTOTAL =					\$ 1,000.00	***************************************
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).					\$	
TOTAL NATIONAL FEE =					\$ 1,000.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property +					\$ 40.00	
TOTAL FEES ENCLOSED =					\$ 1,040.00	
					Amount to be refunded:	\$
					Amount to be	\$ 1,040.00
					charged:	1,040.00
a. A check in the amount of \$ to cover the above fees is enclosed.						
b. Please charge my Deposit Account No. 500799 in the amount of \$ 1,040.00 to cover the above fees.  A duplicate copy of this sheet is enclosed.						
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit t Account No. 500799. A duplicate copy of this sheet is enclosed.						
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.						
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137/2) or (b)) must be filed and granted to restore the International Application to pending status.						
SEND ALL CORRESPONDENCE TO:						
Mark Chao, Ph.D., JD						
Takeda Pharmaceuticals North America, Inc SIGNATURE					- <del></del>	
475 Half Day Road Ma					hao, Ph.D., JD	
Lincolnshire, IL 60069 USA NAME						
(847)383-3372 fax (847)383-3409					,293	
REGISTRATIO					ON NUMBER er No. 23,115	· · · · · · · · · · · · · · · · · · ·

FORM PTO-1390 (REV. 12-2004)

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# JC14 Rec'd PCT/PTO 21 JUL 2005

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

Based on PCT/JP2004/000754

24504 011 1 0 1751 200 170

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Filed:

Intl. Filing 28 JANUARY 2004

Examiner:

tba

1<sup>st</sup> Inventor:

Kazahiro Ohkouchi

THOWEC

For:

**Process for Producing Coated Preparation** 

Batch

Atty. Dkt. No.

3153 US0P

Paper No.

### **CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10**

#### USPS EXPRESS MAIL LABEL. No. EV 524905150 US

**DATE IN:** 

July 21, 2005

#### Itemized Papers/Items:

- 1. This Certificate of Express Mailing and Return Postcard (2 pages)
- 2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
- 3. PCT Request (5 pages)
- 4. Specification total pages (37) including Claims 1-13 (pages 35-36, and Abstract (1 page)
- 5. Declaration and Power of Attorney (4 pages)
- 6. Copies of Forms PCT/IB/301, 304, 306, 308 (6 pages)
- 7. Copy of Cover Page International Application (WO 2004/067001) (1 page)
- 8. Copy of International Search Report (2 pages)
- 9. Preliminary Amendment (2 pages)
- 10. Executed Assignment (2 pages) and Recordation Cover Sheet (1 page X 2)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP PCT P.O. BOX 1450

Commissioner for Patents

Alexandria, VA 22313-1450

on this date, July 21, 2005

Gail I. Wine

Dated: 7/21/09

Takeda Pharmaceuticals North America, Inc. Intellectual Property Department 475 Half Day Road

Lincolnshire, IL 60069 USA